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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,447	12/03/2001	Todd D. Eungard	1001.1492101	5080

7590

12/19/2002

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EXAMINER

PITTMAN, ZIDIA T

ART UNIT

PAPER NUMBER

1725

DATE MAILED: 12/19/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

A-2-4

Office Action Summary

Application N .

10/008,447

Applicant(s)

EUNGARD ET AL.

Examiner

Zidia Pittman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12, 14, 15, 17-19, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 13, 16, 20 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3. 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8 and 24-26, drawn to a guidewire manufacturing assembly, classified in class 606, subclass 108.
- II. Claims 9-23, drawn to a method of forming an atraumatic distal tip on a guidewire, classified in class 228, subclass 224.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be utilized in the production of heat exchangers.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Glenn Seager on December 13, 2002 a provisional election was made without traverse to prosecute the invention of Group II, claims 9-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-8 and 24-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-12, 14, 17-19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Salmon et al (USPN 5,458,585).

Salmon et al teaches a tracking tip for a work element in a catheter system. Figure 2 depicts a work element (guidewire) fitted with an improved tracking tip (atraumatic). The embodiment depicted comprises a tapered wire coil fixed to the distal tip of the work element. Wire coil is fitted with a solder ball at its distal end. The work element can be rotated by the draft shaft. Attached to a proximal end of the drive shaft is a rotation coupling for removable attachment to a drive motor. When the rotation coupling is attached to the drive motor, and the drive motor is actuated, the drive shaft and connected work element experience rotational movement. Wire coil is welded to the work element. The spring-like wire coil provides tracking tip with a degree of flexibility not present in an unmodified work element. The wire coil may be formed by

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wrapping an appropriately chosen wire around a tapered mandrel to achieve a wire coil whose diameter decreases in the distal direction. The tracking tip may be formed as depicted in Figures 3A and 3B. First, a wire of appropriate dimension and material is selected. If desired, the wire may taper, or decrease in diameter, from a proximal end to a distal end. A solder ball may be fixed to the distal end of the wire coil as depicted in Figures 4A and 4B. After the wire ends are clipped and the wire coil ends are ground smooth, wire coil is placed on a holder with distal end facing up as depicted in Figure 4A. Then a solid solder ball of appropriate diameter is dipped into and coated with an appropriate flux material. Solid solder ball is placed onto distal end of coil. When the hot tip of a soldering iron is touched to the solder ball, surface tension causes the rough solder ball to flow to form a smooth, near-perfect sphere as depicted in Figure 4B.

(abstract; Figures 1-4B; column 4 line 8 – column 5 line 20)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salmon et al (USPN 5,458,585) in view of Frechette et al (USPN 5,830,155).

Salmon et al teaches a tracking tip for a work element in a catheter system. Figure 2 depicts a work element (guidewire) fitted with an improved tracking tip (atraumatic). The embodiment depicted comprises a tapered wire coil fixed to the distal tip of the work element. Wire coil is fitted with a solder ball at its distal end. The work element can be rotated by the draft shaft. Attached to a proximal end of the drive shaft is a rotation coupling for removable attachment to a drive motor. When the rotation coupling is attached to the drive motor, and the drive motor is actuated, the drive shaft and connected work element experience rotational movement. Wire coil is welded to the work element. The spring-like wire coil provides tracking tip with a degree of flexibility not present in an unmodified work element. The wire coil may be formed by wrapping an appropriately chosen wire around a tapered mandrel to achieve a wire coil

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whose diameter decreases in the distal direction. The tracking tip may be formed as depicted in Figures 3A and 3B. First, a wire of appropriate dimension and material is selected. If desired, the wire may taper, or decrease in diameter, from a proximal end to a distal end. A solder ball may be fixed to the distal end of the wire coil as depicted in Figures 4A and 4B. After the wire ends are clipped and the wire coil ends are ground smooth, wire coil is placed on a holder with distal end facing up as depicted in Figure 4A. Then a solid solder ball of appropriate diameter is dipped into and coated with an appropriate flux material. Solid solder ball is placed onto distal end of coil. When the hot tip of a soldering iron is touched to the solder ball, surface tension causes the rough solder ball to flow to form a smooth, near-perfect sphere as depicted in Figure 4B.

(abstract; Figures 1-4B; column 4 line 8 – column 5 line 20)

Salmon et al does not teach wherein the work element (guidewire) further comprises a heat shrink tube coupled to the shaft.

Frechette et al teaches a guidewire assembly. The guidewire assembly provides a flexible attachment and method for attaching a necked down proximal end portion of a radiopaque platinum tungsten coiled wire to a tapered portion of a stainless steel core wire using a heat shrinkable and meltable plastic sleeve. (abstract; Figure 3; column 2 lines 1-6, 19-35, 45-51; column 3 lines 27-49)

At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the teachings of Salmon et al with the teachings of Frechette et al in order to ensure that if the core wire breaks, the broken segment does not separate

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from the remaining core wire and yet retains flexibility in a tip section of a guidewire.

(column 1 lines 14-23)

Allowable Subject Matter

Claims 13, 16, 20, and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach a method of forming an atraumatic distal tip on a guidewire including wherein the holding fixture holds the shaft in the horizontal direction and wherein the heat shrink tube stops proximal flow of flux during the step of heating the solder ball.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Quiachon et al (USPN 6,039,743), Hastings et al (USPN 5,873,835), Cope et al (USPN 5,776,079), Quiachon et al (USPN 5,697,380), Nanis et al (USPN 5,695,111), and Smith (USPN 4,634,042) are cited as of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zidia Pittman whose telephone number is (703) 305-1248. The examiner can normally be reached on Monday – Thursday and alternate Fridays from 8:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Dunn, can be reached at (703) 308-3318. The official fax phone number for the organization where this application or proceeding is assigned is (703) 305-7718. The unofficial fax number for art unit 1725 is (703) 305-6078.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

37P
12/13/02



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